K041035

JUN - 9 2004

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

HOFFRICHTER GmbH
Mettenheimer Strasse 12/14
D-19061 Schwerin
Germany
Tel.: +49-385-39925-0
Fax: +49-385-39925-25
E-mail: info@hoffrichter.de

Contact Person: Norbert Küchemann

Position/Title: Sales Manager

Date of Preparation: April 10, 2004

(2) **Trade Name:** TREND 110 CPAP device with Aqua TREND III Humidifier Accessory

Common/Classification Name: VENTILATOR, CONTINUOUS, NON-LIFE-SUPPORTING; HUMIDIFIER, RESPIRATORY GAS (Humidification on Plus Models only)

Product Code(s): BZD, 21 CFR §868.5905
BTT, 21 CFR §868.5450

Class: Class II

(3) **Predicate Device(s):**

- SCALAR/VECTOR CPAP with Humidifier "Plus" option (K014074)
- Fischer and Paykel HC200 CPAP with Heated Humidifier (K973161)
- Invacare Poseidon Passover Humidifier (K003561)

Reason for Submission: New Device

(4) **Description of Device:**

Hoffrichter *TREND 110* devices provide mono-level CPAP treatment levels over the clinician settable range of 4 to 18 cmH_2O.

The *TREND 110* CPAP device is provided in a compact lightweight enclosure for easy bedside use. A 2 x 16 character LCD display with keys on the operator panel provides the user with displayed information about

the treatment level as well as access to menus for soft-start ramp, clinical prescription (set by doctor, PIN code protected) and hours of operation. *TREND 110's* power supply automatically supply adapts to regional mains voltage (115 to 230 VAC).

Heated humidification is available by installing the *AquaTREND III* heated humidifier accessory. A key with LED indicator permits the user to select the humidification level. Moisture contacting materials in the humidifier and therapy tube meet biocompatibility requirements.

Treatment pressure is measured as close as possible to the patient mask by means of a measuring tube integrated into the therapy tubing. This maximizes accuracy and control of pressure and minimizes losses due to the therapy delivery circuit.

TREND 110 has a user selectable ramp function, which starts with a reduced pressure and gradually increases to the treatment pressure to make it more comfortable to fall asleep. The user can adjust the ramp time in 10 minute increments to 0 (no ramp), 10, 20, or 30 minutes.

Standard accessories include treatment tubing with integrated measurement tube and headgear. Commercially available masks and swivels are specified.

Hoffrichter CPAP devices are prescription use devices, and are not intended for life supporting or life sustaining applications.

(5) **Intended use:**

Obstructive sleep apnea (OSA) is a condition caused by closing of the upper airway during sleep. The uvula and soft pallet collapse on the back wall of the upper airway, and when the tongue moves back, the airway is temporarily sealed, causing disruptions in normal respiration and sleep.

Continuous Positive Airway Pressure (CPAP) is an effective treatment for OSA. CPAP devices treat the condition by supplying a constant positive pressure to the airway, most commonly via the nasal passages, in order to prevent the collapse of the soft tissue of the uvula and soft palate during sleep.

Indications for Use:

The TREND 110 device is for treatment of obstructive sleep apnea (OSA) in adult patients weighing at least 30 kg. These devices are not intended for use with ventilator-dependent patients.

The TREND 110 device provides continuous positive airway pressure.

The AquaTREND Humidifier accessory provides humidification of the air delivered to the patient.

(6) **Technological Characteristics:**

The *TREND 110* CPAP device employs the same technological characteristics as the predicate devices. The devices employ a computer controlled blower system which is attached via tubing to a swivel and nasal mask to deliver a prescribed mono-level CPAP treatment to a patient. Devices with humidification employ a hotplate type design to heat a water reservoir to add humidification or a passive (unheated) humidifier.

Hoffrichter CPAP devices employ pressure measurement at the mask via a measurement hose integrated into the breathing hose. This enables improved pressure control and accuracy by the Hoffrichter CPAP devices.

(b) (1) **Non-Clinical Tests Submitted:**

The *TREND 110* and *AquaTREND III* devices were tested in accordance with applicable standards for medical device Electrical Safety, Electromagnetic Compatibility, Shock and Vibration, and Environmental Temperature and Humidity. The CPAP devices passed all of the tests.

Static and dynamic pressure testing and humidification testing was performed in comparison with predicate devices. The Hoffrichter *TREND 110* and *AquaTREND III* devices met specified requirements and were comparable to the applicable specifications of the predicate devices.

Software across all platforms was verified to requirements and validated to meet intended use by parameter and event testing.

(2) **Clinical Tests Submitted:** (None)

(3) **Conclusions from Tests:**

As described in (b)(1) above, all of the testing demonstrated that the Hoffrichter *TREND 110* and *AquaTREND III* CPAP devices are as safe and effective as and perform in a manner equivalent to the predicate devices, the Hoffrichter SCALAR/VECTOR Plus, Fisher and Paykel HC200, and Invacare Poseidon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2004

Hoffrichter GmbH
C/O Mr. Stephen H. Gorski
Consultant
Imagenix, Incorporated
S65 W 35739 Piper Road
Eagle, WI 53119

Re: K041035
Trade/Device Name: Hoffrichter Trend 110 CPAP with AquaTrend III
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 10, 2004
Received: April 21, 2004

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K041035**

Device Name: **Hoffrichter TREND 110: CPAP with AquaTREND Humidifier Accessory**

Indications for use:

The TREND 110 device is for treatment of obstructive sleep apnea (OSA) in adult patients weighing at least 30 kg. These devices are not intended for use with ventilator-dependent patients.

The TREND 110 device provides continuous positive airway pressure.

The AquaTREND Humidifier accessory provides humidification of the air delivered to the patient.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K041035